REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the remarks that follow. Claims 1-13 and 15-27 are pending in the application. Claims 15, 16, 26, and 27 are withdrawn from consideration.

Claims 1-13 and 17-25 stand rejected as anticipated by U.S. Pat. No. 5,658,088 to Bezwada et al. The Examiner alleges that the newly-cited Bezwada patent teaches PEG polymers that are crosslinked. Applicant respectfully traverses this rejection.

Bezwada et al. discloses polyoxaesters containing amines and/or amide groups. These polyoxaesters can optionally be blended with a second polymer. Blending means that the polyoxaester and the further polymer do not react with each other. The polyoxaester or the polymer blends are bioabsorbable and can be processed using numerous methods (e.g., injection or compression molding, solvent casting, etc.) in order to manufacture surgical devices such as clips, staples, sutures, and the like.

The present invention discloses a crosslinked polymeric structure in the form of a PEG hydrogel. The crosslinked polymeric structure is hydrolytically degradable whereby the degradation process is precisely controlled through a combination of the degree of crosslinking and the number, as well as the degree of susceptibility to hydrolysis, of the hydrolytically weak linkages which are introduced between the PEG polymer segments. The hydrogels are degraded to non-toxic PEG fragments, which are usually cleared from the body.

The subject-matter of independent claim 1 is directed to a crosslinked polymeric structure in the form of a hydrogel that swells in water. The polymeric structure comprises only PEG-polymers whereas non-PEG-polymers are absent. The number and the degree of susceptibility to hydrolysis of the hydrolytically weak linkages that are introduced between the PEG polymer segments provide for the degradability.

In contrast, Bezwada et al. teach polyoxaesters or blends of said polyoxaesters with further polymers. The polymers can comprise PEG elements. However, the polyoxaesters disclosed in Bezwada et al. always include non-PEG polymer segments, particularly the

repeating unit R_{12} containing internal amine or amide groups. In hydrogels according to the present invention, non-PEG-polymers are absent, since it is known that non-PEG elements tend to introduce complexity into the hydrogel and the degradation of the matrix often yields undesirable or toxic components that are released into the blood stream when the hydrogels are used *in vivo* for drug delivery (page 4, paragraph [0021] of the description). Since there are no non-PEG-polymers present, the hydrogels advantageously break down to substantially non-toxic PEG fragments that are typically cleared from the body (page 5, paragraph [0023] of the description).

Note that there is an obvious typographical error in the summary section of the Bezwada patent cited by the Examiner. Formula XVI was inadvertently presented with an R_2 repeating unit rather than R_{12}. However, Formula XVI is presented correctly in the abstract and the claims. Also, R_{12} is mentioned at line 41 of column 2, which clearly indicates that Formula XVI in column 2 was supposed to include R_{12}. The clear intent of the Bezwada patent is to provide polymers containing a repeating internal amine or amide group, as set forth in the title and throughout the patent. For at least this reason, Applicant respectfully submits that the cited patent cannot be viewed as an anticipatory reference and reconsideration and withdrawal of the rejection is requested.

Further, Bezwada et al. do not disclose hydrogels as set forth in the pending claims. There is no suggestion in Bezwada that hydrogel materials are desirable. Instead, it is quite clear from the cited patent that hydrogel materials would be viewed as undesirable.

The polyoxaester described in Bezwada et al. are substantially linear polymeric molecules. The addition of coupling agents causes branching of long chains. This can impart desirable properties in the molten state to the polyester pre-polymer (column 4, lines 55 to 62). The consequence of introducing a certain degree of branching is reduction of gelation. In addition, the decrease in viscosity is intended to improve the further processing as an increasing inherent viscosity renders the polyoxaester more and more difficult to use (column 7, lines 56 to 59).

It is important to note, that branching only means, a polymer-chain is not linear but has one or more side-chains, while crosslinking means that two (parallel) polymer-chains are

connected by connecting molecules. This difference is important because cross-linking as it is achieved in hydrogels according to the present invention does not allow further processing.

The cross-linked polymeric structures of the present invention undergo extensive swelling in an aqueous environment. In contrast, the polyoxaesters disclosed in Bezwada et al. are hydrophobic and therefore do not undergo swelling when they come in contact with water. In suture material, swelling is an undesired property. The crosslinking mentioned in Bezwada (column 9, lines 43 to 48) has to be viewed in the context of the entire patent disclosure. Bezwada at al. suggests crosslinking achieved by irradiation to improve the mechanical stability of the polyoxaester (blends), in particular to control undesired swellability. There is nothing in the Bezwada to suggest that formation of a hydrogel, as presently claimed, is desired. For this additional reason, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Applicants also note that a consequence of the swelling in an aqueous environment, which hydrogels according to the present invention undergo, is that the degradation proceeds throughout the whole hydrogel. Polyoxaester materials as taught in Bezwada et al. are mainly degraded on their surface, which greatly reduces their bio-absorbability.

In contrast, the hydrolytic degradation of hydrogels of the present invention can be precisely controlled by the degree of crosslinking, by altering the number methylene groups adjacent to the hydrolytically unstable linkage, and by altering the degree of branching of the PEG-polymer (page 6, paragraph [0030] of the description). For instance, the half life of an ester linkage with one adjacent methylene group is about four days at pH=7 and 37°C. An ester linkage with two adjacent methylene groups has a half life of about 43 days at pH=7 and 37°C (page 6, paragraph [0029] of the description). Bezwada et. al. do not disclose in any way how the degradability of the polymeric materials may be controlled.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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